



NATIONAL DAIRY COUNCIL®

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Dockets Management Branch
(HFA - 305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No. 94P-00360 Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period
67 Federal Register 69171, November 15, 2002

Dear Sir or Madam:

The NATIONAL DAIRY COUNCIL® (NDC) submits the following comments on the docket referenced above.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL® is recognized throughout the nation as a leader in nutrition research and education. NDC appreciates the opportunity to provide comments on FDA's proposed use of a *trans* fat Daily Value footnote in its reopening of comments on trans fatty acid labeling.

NDC is opposed to FDA's proposed footnote: "Intake of *trans* fat should be as low as possible" and the asterisk ("or other symbol") that would appear in the percent Daily Value column of the nutrition Facts Panel¹ and urges the agency not to include this as part of the final rule for *trans* fat labeling for two important reasons:

94P-0036

C2275

¹ Docket No. 94P-0036 Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period 67 Federal Register 69171, November 15, 2002. p. 4 (pdf file).

1. There is a lack of scientific rigor and documentation to support the footnote statement.
2. There is high potential for consumer confusion and further reductions in dairy and other nutrient dense food consumption.
3. Other *trans* fatty acids may have health benefits.

NDC suggests that FDA proceed with finalizing its proposed rule on nutrition labeling of *trans* fat by declaring grams of non-conjugated *trans* fat as a separate line item on the nutrition label (based on FDA's proposed per serving cut point of 0.5 g *trans* fat per serving), *without a footnote under the percent Daily Value column.*

The rationale for our position is provided below.

1. The basis for the proposed trans fat footnote lacks scientific rigor.

The FDA's decision to alter its position on trans fat labeling from their original 1999 proposal, to its current proposal to declare *trans* fatty acid content on a separate line and to include a footnote statement in conjunction with the percent Dairy Value appears to be based entirely on the recommendation provided in the IOM/NAS "Letter Report on Dietary Reference Intakes for *Trans* Fatty Acids"².

It is worth noting that the summary statements in this IOM/NAS report conclude that:

- "There is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD, thus **suggesting** a Tolerable Upper Intake Level (UL) of zero"² and,
- "Nevertheless, it is recommended that trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet"²

As an institution dedicated to sound science and service as an expert resource, NDC questions whether the data on which these conclusions and recommendations are based meet appropriate scientific rigor and whether the weight of the scientific evidence is sufficient to support the proposed trans fat Dairy Value footnote. The above IOM/NAS summary statements are apparently based solely on a best-fit regression of *trans* fatty acid intake and the **LDL:HDL** ratio presented in Figure 8-4 on the IOM/NAS report³.

² "Letter Report on Dietary Reference Intakes for *trans* fatty acids". P. 14. Drawn from the Report on: "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids". Food and Nutrition Board. Institute of Medicine of the National Academies. 2002 by the National Academy of Sciences.

³ IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids". Chapter 8, National Academy Press, Washington, DC, p. 8-61, 2002.

Although the regression plot, on which the IOM/NAS based their conclusions, was reported in a peer-reviewed journal, this paper appeared as a non-peer reviewed “sounding board” commentary^{4,5}. It is of further concern to note that this *commentary* fails to provide a methods section and lacks critical details on the source and nature of raw data and the statistical methods and/or assumptions on which the regression was derived. For example, it is not at all clear whether the best-fit regression line presented in Fig 8-4 of the IOM/NAS report for *trans* fatty acids utilized:

1. The treatment group mean values for LDC and HDL taken directly from the referenced publications⁴ or whether original raw data were utilized.
2. Appropriate weighting factors to account for study design dissimilarities from the referenced publications⁴.

Without this information and with the knowledge that the *commentary* was not peer reviewed⁵, there remains doubt about its conclusions and the scientific rigor that form the basis for the statement: “There is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD, thus *suggesting* a Tolerable Upper Intake Level (UL) of zero”². In light of the public health importance placed by the FDA on the above IOM/NAS *trans* fat recommendations and on which the proposed *trans* fat footnote is based, NDC strongly objects to the use of this *commentary*⁴ as a basis for the proposed footnote. NDC urges the FDA not to establish a precedent of using science that has not been subjected to the rigors of peer review as a basis for nutrition labeling decisions.

2. The proposed *trans* fat footnote has high potential to confuse and frustrate consumers.

The IOM/NAS macronutrient report states that to achieve the suggested Tolerable Upper Intake Level of zero intake of *trans* fatty acids would require “extraordinary changes in patterns of dietary intake”². It also states that such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods, such as dairy products and meats, that contain *trans* fatty acids may result in inadequate intake of protein and certain micronutrients) and unknown and unquantifiable health risks may be introduced by any extreme adjustments in dietary pattern.”² In light of the large number of Americans who are not meeting current calcium recommendations and the failure to consume recommended amount of dairy products by children and adults in the U.S.⁶, NDC is concerned that extraordinary focus on *trans* fatty acids through the

⁴ Ascherio A, Katan MB, Zock PL, Stampfer MJ, Willett WC. 1999. *Sounding Board*: Trans fatty acids and coronary heart disease. N Engl J Med 340: 1994-1998,

⁵ “*Sounding Board* articles are opinion essays. They are similar to editorials but not tied to a particular article. They often present opinions on health policy issues and are normally unsolicited.” New England Journal of Medicine, Help for Authors. <http://www.nejm.org/hfa/articles.asp>.

⁶ NIH consensus Development Program: “Consensus Statements. Osteoporosis Prevention, Diagnosis, and Therapy.” Vol. 17, No. 1, March 27-29, 2000. Website: http://odp.od.nih.gov/consensus/cons/111/111_intro.htm

proposed *trans* fat footnote statement could easily result in consumer confusion and overreaction in an effort to lower *trans* fat in their diet by further reducing consumption of dairy products and other nutrient dense foods. One only needs to reflect on consumer overreaction to dietary recommendations to reduce total fat in their diets as one causative factor that resulted in reduced dairy product consumption in the U.S. and increased consumption of simple sugars and energy, especially in adolescent and adult females⁶.

3. Other *trans* fatty acids may have health benefits.

The IOM/NAS macronutrient report also acknowledges the emerging scientific evidence showing potential health benefits of one group on *trans* fatty acid isomers, i.e., conjugated linoleic acid (CLA)⁷. Although the IOM/NAS report concludes that, "To date, there are insufficient data in humans to recommend a level of CLA at which beneficial health effects may occur"⁷, it particularly points out the consistency and reliability of the anticarcinogenic effects of CLA in animal models, especially for breast cancer⁷. CLA occurs naturally in dairy- and meat-based foods and both feeding practices and biotechnology offer ways to further enhance the levels of these bioactive fatty acid isomers in ruminant animal products such as bovine milk, as well as in common vegetable oils. In light of the potential establishment of the anticarcinogenic benefits of the CLA *trans* fatty isomers in humans, the impact of a *trans* fatty acid footnote that fails to distinguish between "healthy and non-healthy" *trans* fatty acids in food products raises the potential for consumer confusion and mistrust. FDA should provide reassurance or information that the use of the proposed footnote would not be misleading to consumers.

NDC believes that consumers understand factual information presented simply in the current nutrition labeling format. For example, other nutrients without an established Dairy Value, such as sugars and monounsaturated and polyunsaturated fatty, have been declared on food packages since the NLEA regulations were enacted. NDC urges the FDA not to establish a precedent for a footnote of percent Dairy Value in reference to *trans* fat.

Thank you for the opportunity to comment on this important issue.

Sincerely,



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Senior Vice President
Nutrition Research and Scientific Affairs



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⁷ IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids: Chapter 11, National Academy Press, Washington, DC, p. 11-47 - 11-48, 2002.